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EXAMINER	
NEAL, TIMOTHY J	
ART UNIT	PAPER NUMBER
3731	
MAIL DATE	DELIVERY MODE
05/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/779,721	JONN ET AL.	
	Examiner	Art Unit	
	Timothy J. Neal	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,11,12,14-29,31,32,34-44 and 46-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,11,12,14-29,31,32,34-44 and 46-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/24/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendments received on 10/29/2007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 11, 12, 14-23, 25, 27, 31, 32, 34-39, 41-44, and 46-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US 5,259,835) in view of Ballance et al. (US 6,439,789) further in view of MacDonald et al. (US 2004/0142041), Zaffaroni (US 3,731,683) or Podell et al. (US 5,620,702) or Edenbaum et al. (US 4,733,659).

Clark discloses:

Claim 1: a flexible material (Fig 1 Item 30 and Fig 10 Item 30 and Fig 6); an adhesive substance applied over substantially the entire bottom side of said flexible material (Fig 2 Item 40); and an adhesive composition permeated throughout at least a portion of said flexible material (Col 4 Line 14), wherein said polymerizable adhesive composition interacts with and/or solubilizes said adhesive substance (Fig 2).

Claim 2 and 47: said flexible material is a mesh (Col 3 Line 54).

Claim 3: said flexible material comprises perforations or tear lines (Fig 6 Item 52).

Claim 4: said flexible material is flexible and porous (Col 3 Line 35 and Col 3 Line 54).

Claim 5: said flexible material is substantially free of elastin (not stated in disclosure as being present or required for this device).

Claim 6: said flexible material is elastic (Col 3 Line 34).

Claim 11 and 48: said adhesive substance is a pressure sensitive adhesive (Col 4 Line 45, stated as well known in the art by the reference and by the Applicant (paragraph 49 of Specification).

Claim 12 and 49: said pressure sensitive adhesive has a weaker bonding strength than said adhesive composition (Col 4 Line 33).

Claim 13: said adhesive substance does not interact with said adhesive composition (Fig 10).

Claim 18: said adhesive composition substantially covers surfaces on at least said bottom side and a top side of said flexible material (Fig 10).

Claim 19: said adhesive composition substantially does not cover said adhesive substance (Fig 10).

Claim 25: the flexible material is not biodegradable (Col 3 Line 40; polyolefins are considered generally to be non-biodegradable).

Claim 31: said adhesive substance is permeated by said adhesive composition (Col 4 Line 38).

Claim 32: said flexible substrate (does) not include features that penetrate an underlying substrate during use (Fig 8 Item 56).

Claim 34: a method of bonding tissue, comprising: placing a flexible substrate over a section of tissue, wherein said flexible substrate comprises a flexible material and an adhesive substance applied over substantially the entire bottom side of said flexible material (Col 4 Line 14); applying an adhesive composition over and substantially covering at least a portion of the flexible substrate (Col 4 Line 14); and allowing the adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to said tissue (Figs 10 and 19).

Claim 35: said section of tissue includes a wound to be closed (Figs 10 and 19).

Claim 36: said placing comprises: fixing a first portion of said flexible substrate to said section of tissue on a first side of said wound; approximating edges of said wound; and fixing a second portion of said flexible substrate to said section of tissue on a second of said wound opposite said first side of said wound (Figs 10 and 19).

Claim 37: removing said first and second portions of said flexible substrate (Figs 10 and 19).

Claim 38: a third portion of said flexible substrate remains, covering said wound (Figs 10 and 19).

Claim 39: said removing comprises trimming said first and second portions of said flexible substrate (Col 8 Line 23).

Claim 41: said applying comprises: placing a quantity of said adhesive composition on an exposed side of the flexible substrate; and spreading the quantity of

adhesive composition to substantially cover the flexible substrate (Fig 19 and Col 3 Line 50).

Claim 42 and 55: said section of tissue has a length and a width, said length being longer than said width; said wound has a length and a width, said length being longer than said width; and said wound extends lengthwise in a lengthwise direction of said section of tissue (Fig 19).

Claim 43: the flexible material is sterilized (Col 9 Line 30).

Claim 44: the adhesive composition is sterilized (Col 9 Line 43).

Claim 46: a flexible material (Fig 1 Item 30 and Fig 10 Item 30 and Fig 6); an adhesive substance applied over at least a portion of a bottom side of said flexible material (Fig 2 Item 40); and an adhesive composition applied over an entire surface of said flexible material and permeated throughout at least a portion of said flexible material (Col 4 Line 14).

Claim 54: a method of bonding tissue, comprising: placing a flexible substrate over a section of tissue, wherein said flexible substrate comprises a flexible material and an adhesive substance applied over at least a portion of a bottom side of said flexible material (Col 4 Line 14); applying an adhesive composition over and substantially covering an entire surface of the flexible substrate (Col 4 Line 14); and allowing the adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to said tissue (Figs 10 and 19).

Regarding claims 1-44, specifically claims 1, 14-17, 20-29, 40, 46, and 50-54 Clark does not disclose the adhesive covering the entire bottom side of the flexible material; the adhesive being polymerizable, a polymerization initiator or rate modifier for said polymerizable adhesive composition disposed in or on said flexible material; said polymerization initiator or rate modifier is immobilized on said flexible material; a bioactive material disposed in or on said flexible material; said bioactive material is not immobilized on said flexible material, but is soluble or dispersible in said polymerizable adhesive composition; the flexible material is biodegradable; the flexible material and the polymerizable adhesive composition are together not biodegradable; the article is opaque; the article is translucent.

Regarding claims 1-6, 11, 12, 14-23, 25, 27, 31, 32, 34-39, and 41-55, Ballance teaches a 1,1-disubstituted monomer and a cyanoacrylate monomer that are both polymerizable (Col 6 Lines 35-53). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark's adhesive to include Ballance's polymerizable adhesive. Such a modification would provide protective coverage of wounds with a fast-acting surgical adhesive.

Ballance also teaches the use of a polymerization initiator and bioactive material (Col 6 Lines 55-65). Ballance also teaches the initiator being immobilized (Fig 1 Item 120) and the bioactive material being dispersible in the polymerizable composition (Col 7 Line 20). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark's article to include Ballance's

polymerizable initiator and bioactive material. Such a modification would accelerate polymerization and the use of bioactive agents can help the healing process. By keeping the initiator immobilized, the polymerizable adhesive will avoid polymerizing until the desired time, for example, not until after the bandage is in place. The bioactive material being dispersible in the polymerizable composition allows it to reach the wound so that it can be effective; said placing comprises: fixing a first lengthwise end of said flexible substrate to said section of tissue on a first lengthwise end of said wound; approximating edges of said wound; fixing a second lengthwise end of said flexible substrate to said section of tissue on a second lengthwise end of said wound opposite said first lengthwise end of said wound; and a polymerizable adhesive applied to the entire top side of said flexible material.

Regarding claims 1, 34, and 40, MacDonald, Zaffaroni, Podell, and Edenbaum teach an adhesive substance covering substantially the entire bottom surface of a bandage (Figure 1 Item 72 in the MacDonald reference, Figure 1 Item 12 in the Zaffaroni reference, Column 5 Lines 27-49 in Podell, and Column 3 Lines 9-21 in Edenbaum). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark's article to include an adhesive covering the entire bottom side of the flexible material. Such a modification would ease manufacturing and would secure the bandage to the entire surface to which it is being applied. One having ordinary skill in the art would expect the increased adhesive area would improve adhesion.

Regarding claim 27, the Applicant has admitted that biodegradable and non-biodegradable adhesives are known in the art (Paragraph 33 of Specification). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark and Ballance's article to include a non-biodegradable polymerizable adhesive composition. Such a modification would require the bandage to be removed from the wound. This would allow the user to keep the article on the wound until the wound is completely healed. A biodegradable composition may biodegrade prior to complete healing.

Regarding claim 32, a barrier layer to prevent the flow of adhesive into the wound is described in Clark (Fig 8 Item 56). The barrier layer may be used with any of the embodiments, therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify any of Clark's embodiments to include the barrier layer. Such a modification would prevent the adhesive from flowing into the wound.

Regarding claims 46 and 54, Barley, Jr. (US 5,653,769, see relevant art in conclusion) teaches that an adhesive coating should be applied covering the entire surface of the skin. Also, MacDonald and Zaffaroni clearly show the bandage containing the adhesive over the entire top surface as well as the bottom surface (figure 1 in both references). The Examiner thus considers the limitation well known as taught by MacDonald and Zaffaroni and further supported by Barley. Therefore, it would have

been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark's adhesive composition to be applied to the entire top surface of the flexible material. Such a modification would ensure the adhesive permeates the entire material to close the wound.

Claims 24, 26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US 5,259,835) in view of Ballance et al. (US 6,439,789), further in view of MacDonald et al. (US 2004/0142041) or Zaffaroni (US 3,731,683) or Podell et al. (US 5,620,702) or Edenbaum et al. (US 4,733,659) as applied to claim 1 above, further in view of Porzilli (US 5,336,209).

The references above disclose the invention substantially as claimed as stated above. As stated above, the references in combination do not disclose an opaque or translucent bandage that is biodegradable, also wherein the adhesive is biodegradable.

Regarding claims 24, 26, 28, and 29, Porzilli teaches an opaque or translucent bandage that is biodegradable (Claims 5, 13, and 14 and Col 2 Line 35). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark and Ballance's article to include Porzilli's translucent or opaque biodegradable characteristics. Such a modification would either prevent the wound from being seen or allow limited visualization of the wound. A biodegradable substance will degrade overtime and not need to be removed. Cyanoacrylate is a biodegradable adhesive, so the combination of Porzilli's biodegradable bandage with the cyanoacrylate adhesive as discussed above would

satisfy the limitations of claim 26. Also, the Examiner notes that the Applicant has admitted that biodegradable and non-biodegradable adhesives are known in the art (Paragraph 33 of Specification), so upon argument that cyanoacrylate is not biodegradable, the rejection will stand that it would have been obvious to a person having ordinary skill in the art to combine Porzilli's biodegradable material with one of the known biodegradable adhesives so that the article will not need to be removed and is environmentally friendly.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US 5,259,835) in view of Ballance et al. (US 6,439,789), further in view of MacDonald et al. (US 2004/0142041) or Zaffaroni (US 3,731,683) or Podell et al. (US 5,620,702) or Edenbaum et al. (US 4,733,659) as shown above regarding claims 1 and 34, and further in view of Vandruff (US 2002/0193721).

Clark, Ballance, MacDonald, Zaffaroni, Podell, and Edenbaum in combination as stated above (see rejection of claim 1) disclose the substrate of claim 40. These references do not disclose said placing (of said substrate) comprises: fixing a first lengthwise end of said flexible substrate to said section of tissue on a first lengthwise end of said wound; approximating edges of said wound; fixing a second lengthwise end of said flexible substrate to said section of tissue on a second lengthwise end of said wound opposite said first lengthwise end of said wound.

Vandruff teaches said placing comprises: fixing a first lengthwise end of said flexible substrate to said section of tissue on a first lengthwise end of said wound;

approximating edges of said wound; and fixing a second lengthwise end of said flexible substrate to said section of tissue on a second lengthwise end of said wound opposite said first lengthwise end of said wound (Figs 9 and 10). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the method of Clark and Ballance to include Vandruff's placing step. Such a modification would cover a wound in the lengthwise direction with a single article.

Response to Arguments

Applicant's arguments filed 10/29/2207 have been fully considered but they are not persuasive.

There are still issues that have yet to be resolved that the Examiner will now address. The Applicant's amendments and arguments bring up three main issues. The first issue is the use of an adhesive substance covering the entire bottom side of the article. The second issue deals with the use of a polymerizable adhesive that interacts or solubilizes the other adhesive substance. The final issue is the method of applying the article and its polymerizable adhesive.

Regarding the first issue, the Examiner has concluded that when looking at all of the prior art and the knowledge of a person having ordinary skill in the art, the Examiner considers placing an adhesive on the bottom side of the article to cover it completely as obvious. Several references show pads where this is done. Zaffaroni shows a pad with a polymeric matrix 22, a backing 21, and an adhesive coating. The adhesive is designed so that the pad will stick to the patient at the desired location. Clearly the

polymeric matrix must seep through the adhesive layer or there would be no point in having the matrix in the first place. This clearly shows that such adhesives will not prevent the polymerizable adhesive from reaching the wound. The Examiner also notes that Zaffaroni may be used as a primary reference and the polymeric matrix may include an adhesive instead of the described drugs. Also, it is obvious that applying the adhesive to the entire bottom side will enhance the attachment of the article to the skin. Therefore, the limitation that includes applying the adhesive to cover the entire bottom side of the article is obvious.

The second issue also addresses the adhesive. In this instance, the Examiner considers the term "interact" as broad. The two adhesives interact to form the article and to heal the wound. The first adhesive is used to keep the article in place until the second adhesive fully polymerizes. This interaction is required for the device to work in a normal manner.

Finally, the Examiner considers applying the polymerizable adhesive to the entire article obvious. Applying the polymerizable adhesive to the entire article has some advantages. Looking at Zaffaroni again, it would make sense to have the adhesive applied to the entire top surface to ensure the wound is closed as desired. Clark includes tabs that do not contact the wound. However, if combined with Zaffaroni, the articles structure would suggest applying the polymerizable adhesive to the entire article. Not applying the polymerizable adhesive to the entire article may result in a portion of the underlying wound not receiving the adhesive. Without the polymerizable adhesive that portion of the wound will not heal as desired.

When looking at the prior art and the current claims, the Examiner finds no limitation that overcomes the prior art.

The Applicant has amended claim 26 to further describe the degradation of the article. The new claim language does not overcome the prior art and what would have been known to one of ordinary skill. The claim now only requires the article to biodegrade over a period of time. As long as a portion of the article degrades, the claim limitation is met. Biodegradable materials are well known and shown in the prior art; therefore, the claim is obvious.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Barley, Jr. et al. (US 5,653,769) is used to assert the Examiner's claim that covering the entire surface of the wound is well known in the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731